

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOEHRINGER INGELHEIM
PHARMACEUTICALS INC.,
BOEHRINGER INGELHEIM
INTERNATIONAL GMBH,
BOEHRINGER INGELHEIM
CORPORATION and BOEHRINGER
INGELHEIM PHARMA GMBH & CO. KG,

Plaintiffs,

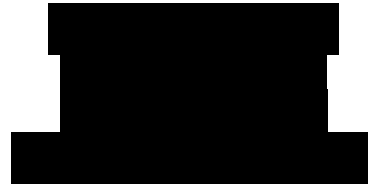
v.

APOTEX INC. and APOTEX CORP.

Defendants.

REDACTED - PUBLIC VERSION

C.A. No. 23-cv-0685-CFC



ORAL ARGUMENT REQUESTED

**OPENING BRIEF IN SUPPORT OF
APOTEX'S MOTION FOR JUDGMENT ON THE PLEADINGS**

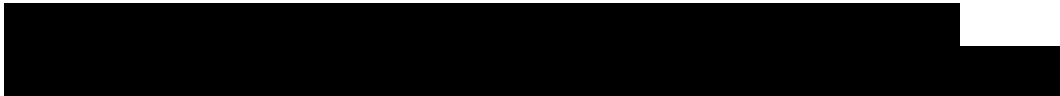
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1	U.S. Pat. No. 9,486,526
2	U.S. Pat. No. 10,034,877

Apotex Responsive Pleading (D.I. 15) Exhibit Designation	Description
A	June 2023 Tradjenta® Label
B	Orange Book Listing for Tradjenta® as of November 9, 2023
C	Apotex's Proposed Label

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Defendants (“Apotex”) respectfully submit this brief in support of their Fed. R. Civ. P. 12(c) motion for judgment on the pleadings on all Counts of Plaintiffs’ Complaint (D.I. 2) concerning U.S. Patent Nos. 9,486,526 (“the 526 patent”) and 10,034,877 (“the 877 patent”) (“the patents-in-suit”).

Apotex’s motion turns on facts admitted by Plaintiffs and apparent on the face of documents incorporated into the pleadings, including the patents-in-suit (D.I. 2, Exs. 1-2), the Tradjenta[®] label (D.I. 15, Ex. A), the Tradjenta[®] Orange Book listing (D.I. 15, Ex. B), Apotex’s proposed label (D.I. 15, Ex. C) (“Apotex’s Label”), and BI’s marketing of Tradjenta[®] (linagliptin tablets, 5 mg).

I. NATURE AND STAGE OF THE PROCEEDINGS.

On June 23, 2023, Plaintiffs (collectively, “BI”) filed their Complaint. (D.I. 2). On November 13, 2023, Apotex filed its Answer, Separate Defenses and Counterclaims. (D.I. 15). On December 11, 2023, BI filed its Answer to Apotex’s Counterclaims. (D.I. 25). Fact discovery has not begun.

II. SUMMARY OF ARGUMENT.

Count I of BI’s Complaint seeks a judicial declaration that the claims of the 526 patent are infringed. All of the 526 patent’s claims recite a method for treating and/or preventing type 2 diabetes mellitus in a patient “ineligible” for metformin due to “contraindication.” (*See* D.I. 2, Ex. 1, Cls. 1-14).

Count II of BI’s Complaint seeks a judicial declaration that the claims of the

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877 patent are infringed. All of the 877 patent’s claims require treating a patient for whom metformin is “inappropriate” due to “contraindication” against metformin. (*See* D.I. 2, Ex. 2, Cls. 1-17).

The Court can and should enter judgment of non-infringement for Apotex based on the admitted facts and record.

First, Apotex does not and will not directly infringe the patents-in-suit because it will not practice the claimed methods—Apotex does not, and does not intend to, treat patients or otherwise administer medicines to patients. Rather, only physicians may prescribe and only patients may directly use Apotex’s Product. BI does not and cannot argue otherwise.

Second, Apotex does not and will not induce infringement of the patents-in-suit. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Third, given the substantial noninfringing use for Apotex’s Product—

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treating patients for whom metformin is not inappropriate/contraindicated—Apotex does not (cannot) contribute to others’ infringement.

III. THE UNDISPUTED FACTS.

A. TRADJENTA® IS APPROVED FOR TREATING TYPE 2 DIABETES IN ADULTS REGARDLESS OF WHETHER THE PATIENT IS ELIGIBLE FOR METFORMIN.

Linagliptin is a drug used to treat type 2 diabetes mellitus (“type 2 diabetes”). (D.I. 15, Ex. A at 1). Side effects associated with type 2 diabetes include renal impairment, which can make administration of metformin—another drug used to treat type 2 diabetes—inappropriate. (D.I. 2, Ex. 1, Col. 2, ll. 43-53).

As reflected in the June 2023 version of the Tradjenta® label, the FDA has approved only the following indication for Tradjenta®:

<p>-----INDICATIONS AND USAGE-----</p> <p>TRADJENTA is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1)</p>
--

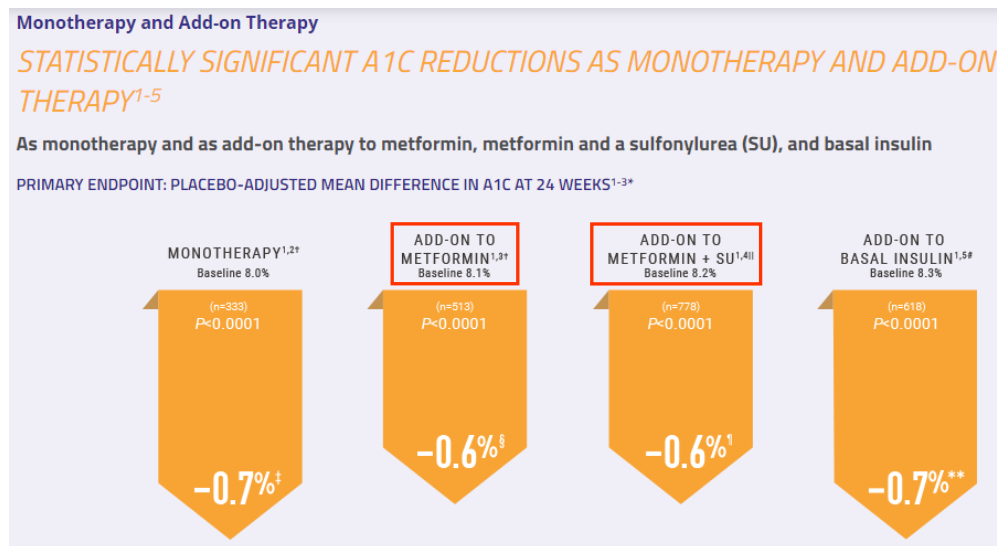
(D.I. 15, Ex. A at 1).

Thus, Tradjenta® is approved for treating type 2 diabetes in adults regardless of whether the patient is eligible for metformin, and regardless of whether metformin is appropriate or contraindicated for the patient. *See id.* The FDA-approved indication for Tradjenta® does not refer to metformin whatsoever. *Id.*

BI promotes Tradjenta® on the internet at www.tradjenta.com (“Tradjenta® Website”). (D.I. 15, Counterclaims ¶ 55). The Tradjenta® Website promotes the admittedly noninfringing use of linagliptin in patients eligible for metformin,

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and/or patients for whom metformin is not contraindicated, *e.g.*:



(*Id.*, Counterclaims ¶ 56 (citing Tradjenta® Website at <https://www.hcp.tradjenta.com/clinical-trials-efficacy>; *id.* at Study Design) (red box emphasis added); D.I. 25, ¶ 56).

B. ALL CLAIMS OF THE PATENTS-IN-SUIT REQUIRE TREATING A PATIENT INELIGIBLE FOR METFORMIN.

The 526 patent (“Treatment for Diabetes in Patients Inappropriate for Metformin Therapy”) issued on November 8, 2016 with 14 claims. (D.I. 2, Ex. 1). Claims 1-7¹ and 10-12 recite a method for treating and/or preventing type 2 diabetes in a patient where “metformin therapy for said patient is ineligible due to contraindication against metformin;” claims 8, 13 and 14 recite “metformin

¹ A dependent claim incorporates all of the limitations of the independent claim on which it depends, and cannot be infringed unless each and every element of the underlying independent claim is also infringed. *Forest Lab ’ys, Inc. v. Abbott Lab ’ys*, 239 F.3d 1305, 1310-11 & n.3 (Fed. Cir. 2001).

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therapy is ineligible due to contraindication against metformin;” and claim 9 recites a method for treating a patient “*who is ineligible for metformin therapy due to contraindication against metformin.*” (See *id.*, Cls. 1-14) (emphasis added).

The 877 patent (“Treatment for Diabetes in Patients Inappropriate for Metformin Therapy”) issued on July 31, 2018 with 17 claims. (D.I. 2, Ex. 2). Claims 1-11 recite a method for treating a patient for whom *metformin therapy is inappropriate due to at least one contraindication against metformin;*” Claims 12-14 recite treating diabetes “in a patient for whom *metformin therapy is inappropriate due to at least one contraindication;*” Claims 15-16 recite a method for treating a patient “having renal impairment and for whom *metformin therapy is contraindicated for renal impairment;*” Claim 17 recites a method for treating a patient “having renal impairment and for whom *metformin therapy is contraindicated for renal impairment...wherein the patient is ineligible for metformin therapy.*” (See *id.*, Cls. 1-17) (emphasis added).

Thus, *all* claims of the patents-in-suit require a method for treating a patient with linagliptin *who is ineligible for metformin.*

BI admitted as much in the “use codes” it submitted to the FDA for listing in the Orange Book. See *Caraco Pharm. Lab’ys, Ltd. v. Novo Nordisk*, 132 S.Ct 1670, 1676 (2012) (“[T]he regulations [] require that, once an NDA is approved, the brand provide a description of any method-of use patent it holds,” which “is

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known as a use code...submit[ted] on FDA Form 3542.”).

For the 526 patent, BI submitted use code U-1915—“[m]ethod of treating type 2 diabetes mellitis in patients with severe chronic renal impairment and who are ineligible for metformin therapy by administering linagliptin.”). For the 877 patent, BI submitted use code U-2347—“[t]reatment of type 2 diabetes mellitis in a patient with renal impairment and for whom metformin therapy is inappropriate by administering linagliptin without dose adjustment.” (D.I. 15, Counterclaims ¶¶ 68-72; *id.*, Ex. B).

[REDACTED]

Apotex is a pharmaceutical company and does not directly treat patients. (D.I. 15, ¶ 11). BI does not, because it cannot, allege that Apotex treats patients or otherwise practices the method of treatment claimed by the patents-in-suit. (*See generally* D.I. 2; D.I. 25, ¶ 97).

Apotex filed ANDA No. 218552 to obtain FDA approval to engage in the manufacture, use, and sale of Linagliptin Tablets, 5 mg. (D.I. 15, ¶ 28).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

Pursuant to 21 U.S.C. § 355(j)(2)(A)(v), Apotex's Label is based upon the TRADJENTA[®] label, [REDACTED]

[REDACTED]

[REDACTED]

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Courts, including this District, have used Rule 12(c) motions to dispose of Hatch-Waxman claims, especially where, as here: (i) each patent claim asserted

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requires a particular element; and (ii) the proof of noninfringement is established by evidence the pleadings provide or incorporate including the ANDA itself. *See, e.g., Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012) (affirming Hatch-Waxman Rule 12(c) dismissals); *Ferring Pharms. Inc. v. Lupin Inc.*, No. 19-cv-913-RGA, 2020 WL 3414750, *3-4 (D. Del. June 22, 2020) (granting Rule 12(c) motion for judgment of no induced infringement of method claims based on proposed ANDA label); *Eagle Pharms., Inc. v. Slayback Pharma LLC*, 382 F.Supp.3d 341, 345-347 (D. Del. 2019) (Connolly, J.) (granting Rule 12(c) motion for judgment of noninfringement); *Cumberland Pharms. Inc. v. Innopharma, Inc.*, No. 12-618-LPS, 2013 WL 5945794, at *3 (D. Del. Nov. 1, 2013) (granting Rule 12(c) motion for judgment of noninfringement).

The Court is well-versed in the Rule 12(c) standard for judgment on the pleadings. Briefly, “[a] motion for judgment on the pleadings under Rule 12(c) is analyzed under the same standards that apply to a Rule 12(b)(6) motion.” *Wolffington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 195 (3d Cir. 2019) (quotation omitted). The Court may consider, not only the pleadings, but also “document[s] integral to or explicitly relied upon” in the pleadings. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

“A motion for judgment on the pleadings will be granted, pursuant to [Rule] 12(c), if, on the basis of the pleadings, the movant is entitled to judgment as a

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matter of law.” *DiCarlo v. St. Mary Hosp.*, 530 F.3d 255, 262 (3d Cir. 2008). As such, “[t]he court will accept the complaint’s well-pleaded allegations as true, and construe the complaint in the light most favorable to the nonmoving party, but will not accept unsupported conclusory statements.” *Id.* at 262-63.

A. BI CANNOT STATE A CLAIM FOR DIRECT INFRINGEMENT.

Despite alleging infringement under 35 U.S.C. § 271(a), BI does not, because it cannot, allege that Apotex treats patients or otherwise directly practices the method claims of the patents-in-suit. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364-65, 1363 n.7 (Fed. Cir. 2003) (finding Warner-Lambert had no cause of action against Apotex for direct infringement for method claims given that “pharmaceutical companies do not generally treat diseases; rather, they sell drugs to wholesalers or pharmacists, who in turn sell the drugs to patients possessing prescriptions from physicians.”). Indeed, BI tacitly admits Apotex does not directly infringe the claimed methods of treating type 2 diabetes. (D.I. 2, ¶ 11 (alleging that “Apotex Inc. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs”)). The Court should enter judgment of no direct infringement for Apotex.

Therefore, BI’s infringement claims turn on whether BI can state a claim for induced infringement under § 271(b) or contributory infringement under § 271(c)—issues the Court may decide on the pleadings alone. *See, e.g., Bayer,*

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676 F.3d at 1326 (affirming Rule 12(c) judgment on the pleadings of no induced infringement).

As shown below, BI cannot state a claim under either § 271(b) or (c).

B. BI CANNOT STATE A CLAIM FOR INDUCED INFRINGEMENT.

BI's induced infringement claim fails as a matter of law for at least two independent reasons:

1. Apotex's Label does not encourage, recommend or promote infringement; and
2. there are substantial noninfringing uses, which vitiates the required intent for induced infringement.

Therefore, Apotex is entitled to judgment on the pleadings as to BI's induced infringement claim for both the 526 and 877 patents.

1. Apotex Cannot Induce Infringement Because Its Label Does Not Encourage, Recommend, or Promote the Claimed Uses.

Apotex is entitled to a judgment of noninfringement because Apotex's Label does not encourage, recommend, or promote performance of the claimed uses of the patents-in-suit.

“To prevail on a theory of induced patent infringement, a plaintiff must prove (1) direct infringement and (2) that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute infringement.” *Genentech, Inc. v. Sandoz, Inc.*, 592 F. Supp. 3d 355, 364 (D. Del. 2022) (Andrews, J.) (internal

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quotation marks omitted) (Hatch-Waxman case: finding no inducement where defendant's label recommended a non-infringing use and merely allowed an infringing use). *See also HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 701 (Fed. Cir. 2019) ("The focus is not on whether the instructions describe the mode of infringement, but rather on whether the 'instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent.'") (quoting *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)).

In the ANDA context, the Federal Circuit has made clear that the patentee must prove that the ANDA applicant will actually promote or encourage others, here physicians or patients, to infringe the patent by using the drug for the patented use. *Warner-Lambert*, 316 F.3d at 1364-65; *see also Takeda Pharm.*, 785 F.3d at 631 ("In the Hatch-Waxman Act context...[t]he label must encourage, recommend, or promote infringement."). "When proof of specific intent depends on the label accompanying the marketing of a drug inducing infringement by physicians, the label must encourage, recommend, or promote infringement." *Genentech, Inc.*, 592 F. Supp. 3d at 364 (Andrews, J.).

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2. Apotex Cannot Induce Infringement Given the Substantial Noninfringing Use of Treating Patients Eligible for Metformin.

Further, intent to induce infringement cannot be inferred when there are substantial non-infringing uses for the drug. *Warner-Lambert*, 316 F.3d at 1365; *see also Allergan, Inc. v. Alcon Lab'ys, Inc.*, 324 F.3d 1322, 1332-33 (Fed. Cir. 2003). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As such, it cannot be disputed that administering Apotex's Product to patients eligible for metformin constitutes a substantial non-infringing use, which entirely undermines the required scienter for induced infringement. This provides another reason BI's induced infringement claim fails.

3. BI's Complaint and Answer to Apotex's Counterclaims Show That Apotex Is Entitled to Judgment of No Inducement.

BI's Complaint contains only unsupported allegations, and its Answer to Apotex's Counterclaims does not point to any promotion/encouragement of the infringing use in Apotex's Label—therefore, Apotex is entitled to a judgment on the pleadings of no inducement.

a. BI's Complaint Contains Only Unsupported Legal Conclusions.

BI's Complaint contains only "threadbare recitals" of "mere conclusory statements," which are not entitled to an assumption of truth as a matter of law.

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See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). In fact, BI does not allege *any* facts in its Complaint that support its “[o]n information and belief” legal conclusion that “the offering to sell, sale, and/or importation of the Apotex ANDA Product by Apotex would actively induce infringement” of the 526 and 877 patents. (*See* D.I. 2, ¶¶ 46, 56).

Allegations contradicted by documents incorporated into the pleadings are entitled to no weight: “[w]here there is a disparity between a written instrument annexed to a pleading and an allegation in the pleading based thereon, the written instrument will control.” *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994); *see also Syncsort Inc. v. Sequential Software, Inc.*, 50 F. Supp. 2d 318, 325 (D.N.J. 1999) (“Legal conclusions made in the guise of factual allegations [] are given no presumption of truthfulness.”).

In sum, BI’s unsupported “[o]n information and belief” allegations should be disregarded as a matter of law.

b. BI’s Answer to Apotex’s Counterclaims Does Not Point to Any Promotion/Encouragement of an Infringing Use.

Apotex’s Counterclaims set forth the contents of Apotex’s Label—and the basis for this Rule 12(c) motion—in detail. See generally D.I. 15 Counterclaims at ¶¶ 77-111. However, despite the clear notice of this motion, BI’s Answer to Apotex’s counterclaims fails to identify anything in Apotex’s Label that encourages or promotes treating a patient who is ineligible for metformin with

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linagliptin, much less instructs such an infringing use. Rather, BI's answer only repeatedly:

■ [REDACTED]

[REDACTED]

- (ii) references a Glucophage® (metformin) package insert (D.I. 25 Ex. 1) *for a different drug*, which states that severe renal impairment is a contraindication to taking Glucophage®; and

■ [REDACTED]

[REDACTED]

(D.I. 25, ¶¶ 74, 75, 76, 77, 79, 80, 81).

BI appears to argue that physicians may understand that Apotex's Product can be safely prescribed to patients ineligible for metformin (and will thus prescribe Apotex's Product to patients ineligible for metformin). But even assuming that such an argument is factually correct, it is beside the point and fails legally—the mere possibility of infringement by others “raise[s] no genuine issue of material fact.” *Warner-Lambert*, 316 F.3d at 1364.²

² See also *Shire LLC v. Amneal Pharms., LLC*, No. 11-3781 (SRC), 2014 WL 2861430, at *5 (D.N.J. June 23, 2014) (“[t]he problem is that the statement that the medication may be taken with or without food cannot be reasonably understood to be an instruction to engage in an infringing use. As Defendants contend, it is indifferent to which option is selected. At most, it may be understood to permit an infringing use, but permission is different from encouragement.”) (granting summary judgment of no inducement).

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Indeed, even permitting or describing an infringing use is not enough—the Federal Circuit has made crystal clear that “[m]erely describ[ing] an infringing mode is not the same as recommend[ing], encourag[ing], or promot[ing] an infringing use, or suggesting that an infringing use should be performed.” *Takeda Pharm.*, 785 F.3d 631 (quotation omitted).

Further, a label that “merely provides physicians with multiple...options, some covered by the Asserted Patents and some not, and leaves [the choice of options] to the physician’s clinical judgment” does not evince specific intent. *Genentech, Inc.*, 592 F. Supp. 3d at 368. *See also HZNP Meds.*, 940 F.3d at 702 (no intent to induce infringement where label’s instructions were broader than claimed method, and did not require users to performed claimed method); *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642, 647 (D. Del. 2022) (Andrews, J.) (granting generic company’s motion to dismiss: “[T]he broader category [included in the label] simply includes both infringing and non-infringing uses, without ‘specifically encourage[ing]’ the use of the generic for the non-infringing uses....”); *see also H. Lundbeck A/S v. Lupin Ltd.*, Nos. 2022-1194, -1208, -1246, 2023 WL 8462010, at *5-9 (Fed. Cir. Dec. 7, 2023) (affirming no inducement or contributory infringement where ANDA label instructed use of vortioxetine to treat major depressive disorder; patent claimed method of treating depressed patients who had previously taken medication but had to cease due to

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adverse events, which plaintiff argued was included in indication and not an off-label use).

Apotex's Label simply does not "encourage, recommend, or promote infringement," and a mere possibility of infringement cannot form the basis for an inducement claim. Thus, BI's unsupported claim for induced infringement fails as a matter of law.

C. BI CANNOT STATE A CLAIM FOR CONTRIBUTORY INFRINGEMENT.

BI's claim for contributory infringement also fails as a matter of law. "To establish contributory infringement, the patent owner must show," among other things, that the accused product "has no substantial noninfringing uses." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010); 35 U.S.C. § 271(c). BI cannot make that showing because Apotex's Product, like Tradjenta[®], is suitable for administration to diabetes patients who are eligible for metformin, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Apotex's Linagliptin Is Suitable for the Admittedly Noninfringing Use of Treating Diabetes Patients Eligible for Metformin.

First, given the clear claim language of the patents-in-suit (e.g., treating a patient "who is ineligible for metformin therapy due to contraindication against

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metformin”), there also can be no dispute that administering Apotex’s Product to a diabetes patient eligible for metformin is a noninfringing use. *See In re Bill of Lading Transmission and Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012) (“formal claim construction is not required to reach the conclusion that...[Defendant’s] products can be used for non-infringing purposes.”).

There also can be no dispute that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Therefore, Apotex’s Product is suitable for a noninfringing use.

2. Treating Diabetes Patients Eligible for Metformin is a Substantial Non-Infringing Use.

Where, as here, a product is “undisputedly capable of non-infringing use, the question of contributory infringement turns on whether the non-infringing use is substantial.” *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009).

The bar for substantiality is not high. In the context of a claim of contributory infringement, “a substantial non-infringing use is any use that is ‘not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.’” *Bill of Lading*, 681 F.3d at 1337 (quoting *Vita-Mix*, 581 F.3d at 1327). *See also Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 442 (1984)

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(“Unless a commodity ‘has *no use* except through practice of the patented method,’ the patentee has no right to claim that its distribution constitutes contributory infringement.”) (emphasis added) (quotation omitted).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] it is apparent on the face of Apotex’s Label that administering its ANDA Product to patients eligible for metformin is a substantial noninfringing use.

This conclusion is further bolstered by the fact that BI expressly markets its Tradjenta[®] product for use in patients eligible for metformin (D.I. 15, Counterclaims ¶ 56 (citing Tradjenta[®] Website at <https://www.hcp.tradjenta.com/clinical-trials-efficacy>; *id.* at Study Design); *see also* D.I. 25, ¶ 56).

As such, there can be no true dispute that Apotex’s Product is suitable for a substantial noninfringing use, and BI’s allegation of infringement under 35 U.S.C. 271(c) must fail. *See Bill of Lading*, 681 F.3d at 1339 (affirming dismissal of § 271(c) claim due to substantial noninfringing use); *Warner-Lambert*, 316 F.3d at 1365 (concluding that product used in noninfringing manner had substantial

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noninfringing uses).

c. BI's Unsupported Legal Conclusions Again Should Be Given No Weight, and Its Answer Does Not Show the Absence of a Substantial Nonfrinining Use.

As with its allegations of induced infringement, BI's Complaint contains only unsupported legal conclusions that Apotex will contribute to infringement by others—BI alleges “[o]n information and belief” that “the offering to sell, sale, and/or importation of the Apotex ANDA Product would contributorily infringe” the 526 and 877 patents. (*See* D.I. 2, ¶¶ 44, 54). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

V. CONCLUSION.

For these reasons, Apotex respectfully requests that the Court enter judgment of non-infringement under Rule 12(c).

Dated: December 13, 2023

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CERTIFICATION OF WORD COUNT

The undersigned counsel certifies that the foregoing document contains 4994 words. Approximately 100 words were manually counted in images, and the remaining 4894 words were counted using Microsoft Word. Any text not appearing in images is in Times New Roman 14-point type.

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CERTIFICATE OF SERVICE

I, Megan C. Haney, Esquire, hereby certify that, on December 13, 2023, a copy of OPENING BRIEF IN SUPPORT OF APOTEX'S MOTION FOR JUDGMENT ON THE PLEADINGS was served on the following counsel via the manner indicated:

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